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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,578	03/01/2006	Derek Hart	18656	6562

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Leopold Presser
Scully Scott Murphy & Presser
400 Garden City Plaza
Ste 300
Garden City, NY 11530

EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,578	HART ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-29* is/are pending in the application.

4a) Of the above claim(s) *3 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-17 and 19-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17 and 19-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/06; 8/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I claims 1, 2, and 4-28, with traverse, filed July 7, 2008 is acknowledged and has been entered. Claim 18 has been cancelled. Claims 3 and 29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-17 and 19-29 are pending. Claims 1, 2, 4-17, and 19-28 are under examination.

2. Upon further consideration, the requirement for election of species set forth in the restriction requirement has been withdrawn

3. Applicant traverses the restriction requirement on the grounds that Groups I and II are not independent and distinct, but rather are related; and that Groups I and III and Groups II and III, although each are related as process of making and product made, are all merely different aspects of a single invention, and as such are not patentably distinct inventions from the other. Applicant further contends that the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application and cites In re Kuehl stating, "[T]his interest is consistent with the practical reality that a sufficiently detailed disclosure claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention."

In response, Applicant is incorrect in stating that Examiner acknowledged Groups II and III as process of making and product made. As properly set forth in the restriction requirement, Groups II and III are related as product and process of using the product.

In response to Applicant's traversal, it is reiterated that Groups I and II are independent and distinct , Group I being drawn to characterizing and isolating a population of dendritic cells and Group II being a diagnostic method which determines certain specific dendritic cell surface antigens and correlates their levels to indicate disease; Group III being related to Group I as process of making and product made; and Group III being related to Group II as a product and a process of using, i.e. in a diagnostic method. As such, it is noted each one of Groups I and II are patentably distinct methods and that Group III is a statutorily distinct product; hence, restriction for examination purposes as indicated is proper. In addition, literature search for each method and product is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

In response to Applicant's contention that Groups I-III are different aspects, i.e. variations, of a single invention and are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the different aspects/species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In response to the argument "[W]e believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in a manner required by 35 U.S.C. 113 all aspects of what they regard as their invention; regardless of the number of statutory classes involved. In re Kuehl, 177 USPQ 250, 256 (CCPA 1973)", the Patent Office is given statutory authority to require restriction if the number of statutory classes and structural requirements are such that examination and search process of the inventions impose serious undue burden to the Examiner. This authority is not contrary to the principle stated in In re Kuehl (supra) in that restriction does not prevent applicants from presenting any number of claims covering numerous statutory classes if they choose. Instead, restriction merely permits the Office to limit its examination to one claimed invention per application.

Therefore, for reasons aforementioned, the restriction requirement restricting the claims to three different patentably distinct inventions is being maintained. Claims 1-17 and 19-29 are pending. Claims 1, 2, 4-17, and 19-28 are under examination

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 4-17, 19-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (ii) is ambiguous because the preamble appears to require characterization of cells in a specific subclass of dendritic cells whereas step (ii) recites "detecting the presence of [any or all] dendritic cell immunogen-immunointeractive molecule complexes and the absence of [any or all] non-dendritic cell immunogen-immunointeractive molecule complexes." Accordingly, it is unclear how the specific subclass in the preamble is characterized using any and all combinations of dendritic cell immunogen-specific immunointeractive molecules and non-dendritic cell immunogen-specific immunointeractive molecules encompassed in the claim. Perhaps, Applicant intends, "detecting the presence of specific defined dendritic cell immunogen-immunointeractive molecule complexes and the absence of specific defined non-dendritic cell immunogen-immunointeractive molecule complexes."

Claim 1, step (iii) is vague and indefinite in reciting, "based at least in part on" because the phrase "at least in part" includes elements not actually disclosed (those encompassed outside of "at least in part"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 2, steps a), b), c), and d) are vague and indefinite in reciting, "based at least in part on" because the phrase "at least in part" includes elements not actually disclosed (those encompassed outside of "at least in part"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 2, step d) is indefinite in relation to step e) because step e) requires "calculating the number of cells in the subclass of dendritic cells … created in step d)" whereas it is unclear how such calculation is performed if step d) is recited as "optional" which encompasses not having to perform step d).

Regarding claim 6, the phrase "functional equivalents" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "equivalents"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Regarding claim 7, the phrase "chemical equivalents" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "equivalents"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Claim 8 recites confusing and improper Markush language in reciting, "...immunogens are selected from the group comprising." Perhaps, Applicant intends, "...immunogens are selected from the group consisting of."

Claim 22 recites confusing and improper Markush language in reciting, "...immunogens are selected from the group comprising." Perhaps, Applicant intends, "...immunogens are selected from the group consisting of."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4-12, 16, 17, 19, and 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohrgruber et al. (Survival, Maturation, Function of CD11c- and CD11c+ Peripheral Blood Dendritic Cells Differentially Regulated by Cytokines, The Journal of Immunology 163: 3250-3259 (1999)).

Kohrgruber et al. teach that two types of dendritic cells (DC) are circulating in human blood cells and can be identified by their differential expression of the myeloid CD11c antigen and that the two diverse DC types respond to T cell-derived cytokines in a differential manner (Abstract). Specifically, Kohrgruber et al. teach a method of characterizing a subclass of dendritic cells in a biological cell sample derived from human subjects. In practice, the cell sample is contacted with two or more immunointeractive molecules (antibodies or Ab) that are directed against DC immunogens (antigens or Ag) and non-dendritic cell (NDC) antigens, to thus form DC antigen-antibody and NDC antigen-antibody complexes. The resulting mixture is then detected for the presence of specific DC Ag-Ab complexes and the absence of specific NDC Ag-Ab complexes whereupon analysis is performed by isolating DCs by morphological characteristics (Figure 3); therefrom, isolating DCs having absence of expression of certain NDCs by centrifugation, counter current elutriation, and immunomagnetic (MACS) depletion of NDC fractions (p. 3251, col. 1 and 2; and Figure 1). Further therefrom, DCs having expression of certain DCs are isolated and

calculated by FACS analysis so as to determine specific subclass of dendritic cells. Kohrgruber et al. specifically teach analysis of DCs within the subclass of dendritic cells based on the presence of predetermined DC Ag/Ab complexes and the absence of predetermined NDC Ag/Ab complexes, in order to thus obtain a characterization of the subclass of dendritic cells (p. 3252, col. 2 and p. 3258, col. 1). The dendritic cell immunogens include any one of CD45RA (CD45 isoform), CDRO (CD45 isoform) HLA-DR, CD11c, CD123 (IL-Rα), CD16, CD83, and CD40 (p. 3250, col. 2 and p. 3251, col. 1 and 2). The non-dendritic cell immunogens include any one of CD3, D19, CD14, CD56, CD11b, and CD34 (p. 3251, col. 2). Kohrgruber et al. specifically found that freshly isolated DC from PBMC by immunodepletion are mainly CD11c-CD45RA+CD45RO- and those isolated from cultured PBMC are largely CD11c+CD45RA-CD45RO+ (p. 3250, col. 2). Accordingly, Kohrgruber et al. is deemed to anticipate the claimed invention.

7. Claims 1, 2, 4-12, 16, 17, and 19-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Summers et al. (Phenotypic Characterization of Five Dendritic Cell Subsets in Human Cells, American Journal of Pathology 159 (1): 285-296 (July 2001)).

Summers et al. identify, quantify and characterize DC subsets from a human biological sample (tonsil and normal blood) derived from human subjects based on their expression of HLA-DR, CD11c, CD13, and CD123 antigens in relation to their expression of DC-associated differentiation/activation antigens and co-stimulator molecules including CD83, CM-RF44, and CMRF-56 (Abstract and p. 286, col. 2). In

practice, the sample is contacted with two or more immunointeractive molecules (Ab) that are directed against DC immunogens (Ag) and NDC antigens, to thus form DC antigen-antibody and NDC antigen-antibody complexes. Summers et al. specifically teach detecting for the presence of and performing an analysis of the cells within the subclass of dendritic cells based on the presence of predetermined DC Ag/Ab complexes and the absence of predetermined NDC Ag/Ab complexes, in order to thus obtain a characterization of the subclass of dendritic cells. Analysis is performed by isolating DCs (by morphological characteristics) (p. 289, col. 2); therefrom, isolating DCs having absence of expression of certain NDCs by immunomagnetic depletion (MACS and FACS); and further therefrom, isolating DCs having expression of certain DCs using FACS; and then calculating the number of cells in the subclass of dendritic cells ultimately created or isolated (p. 286-288). The dendritic cell immunogens include any one of CD45 antigen including RA, RB, and RO isoforms, HLA-DR, CD123, CD11c, CD16, CD1b/c, CD83, CD40, CMRF-44, and CMRF-56 (Abstract; 286, col. 2; p. 288; and Table 2). The non-dendritic cell immunogens include any one of CD3, CD19, and CD14 (p. 285, col. 1; p. 286, col. 1; and p. 288-291). Accordingly, Summers et al. is deemed to anticipate the claimed invention.

8. Claims 1, 2, 3-17, 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzionek et al. (BCDA2, BCDA3, BCDA4: Three Markers for Distinct Subset of Dendritic Cells in Human Peripheral Blood, The Journal of Immunology 165: 6037-6046 (2000)).

Dzionek et al. teach a method of characterizing cells in a subclass of dendritic cells in a biological cell sample (blood) derived from human subjects by generating antibodies that are directed against BCDA2, BCDA3, and BCDA4 antigens. BCDA2, BCDA3, and BCDA4 antigens are specific markers for certain subsets of blood dendritic cells (Abstract). In practice, the sample is contacted with two or more immunointeractive molecules (Ab) that are directed against DC immunogens (Ag) and NDC antigens, to thus form DC antigen-antibody and NDC antigen-antibody complexes. Dzionek et al. specifically teach detecting for the presence of and performing an analysis of the cells within the subclass of dendritic cells based on the presence of predetermined DC Ag/Ab complexes and the absence of predetermined NDC Ag/Ab complexes, in order to thus obtain a characterization of the subclass of dendritic cells. Analysis is performed by isolating DCs by morphological characteristics (p. 6042); therefrom, isolating DCs having absence of expression of certain NDCs (MACS); and further therefrom, isolating DCs having expression of certain DCs; and then calculating the number of cells in the subclass of dendritic cells ultimately created or isolated (FACS). The dendritic cell immunogens include any one of CD45 including RA and RO isoform, HLA-DR, CD1a/cCD123, CD11c, BCDA2, BCDA3, BCDA4, CD16, CD83, CD40, CMRF-44, and CMRF-56 (p. 6037, p. 6038, Table 1, and Table 2). The non-dendritic cell immunogens include any one of CD3, CD19, CD14, CD11b, and CD34 (p. 6037, col. 1; p. 6038, col. 1, Figure 1, and Table 2). Accordingly, Dzionek et al. is deemed to anticipate the claimed invention.

9. No claims are allowed.

Remarks

10. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Olweus et al. (Dendritic Cell Ontogeny: A Human Dendritic Cell Lineage of Myeloid Origin (Proc. Natl. Acad. Sci. 94: 12551-12556 (November 1997)) teach that a large subset of DC in the T-cell dependent areas of human lymphoid organs are non-activated and belong to a separate lineage that can be identified by high levels of IL-3Ra, wherein the IL-3Ra progenitors are of myeloid origin (Abstract and Table 1).

Willmann et al. (US Patent 6,495,333) disclose methods for isolating dendritic cells and then determining dendritic cell immune function by measuring intracellular cytokine expression.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

August 8, 2008